

## **REMARKS**

This application has been reviewed in light of the Final Office Action mailed on February 5, 2004. Claims 24-46 are pending in the application with Claims 24, 31 and 36 being in independent form. By the present amendment, Claim 25 has been canceled, Claims 24, 26, 27, 28, 31 and 36 have been amended and Claim 38 has been added.

In the Final Office Action, all the independent claims were rejected under 35 U.S.C. §§102(b) and 103(a) as being anticipated and unpatentable over prior art references. More specifically, Claims 24-29, 31-34 and 36-37, which include independent Claims 24, 31 and 36, were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,624,382 issued to Oppelt et al. on April 29, 1997 (“Oppelt et al.”); and Claims 24-29, 31-34 and 36-37, which also include independent Claims 24, 31 and 36, were rejected under 35 U.S.C. §103(a) as being unpatentable over Oppelt et al. in view of U.S. Patent No. 4,957,099 issued to Hassler on September 18, 1990 (“Hassler”) and U.S. Patent No. 5,078,144 issued to Sekino et al. on January 7, 1992 (“Sekino et al.”).

Additionally, in the Final Office Action, Claims 30 and 35 were rejected under 35 U.S.C. §103(a) as being unpatentable over Oppelt et al. or alternatively, Oppelt et al. in view of Hassler and Sekino et al. as applied to Claim 24 above, and further in view of Fry et al. (of record).

By the present amendment, independent Claims 24, 31 and 36 have been amended to better define Applicants’ invention and to overcome the cited rejections. Accordingly, it is believed that all pending claims, namely, Claims 24 and 26-40, which include

independent Claims 24, 31 and 36, recite subject matter which is patentably distinct over the disclosure of the cited prior art references.

In particular, Claim 24 has been amended to recite:

An apparatus for treatment of subcutaneous tissue comprising: means for generating ultrasonic vibrations; a substantially plano-concave lens disposed immediately adjacent the means for generating ultrasonic vibrations to focus the ultrasonic vibrations at a focal point within the tissue; a chamber configured to at least partially enclose the means for generating ultrasonic vibrations and the substantially plano-concave lens and being uniformly pressurized therein during treatment, wherein the means for generating ultrasonic vibrations includes a plurality of generator means for generating ultrasonic vibrations, wherein each of the plurality of generator means is substantially equally spaced from an adjacent one along a substantially semi-circular plane, and wherein a focal plane of at least one generator means is transverse to a portion of the chamber; and means for moving the focal point. (Emphasis added)

Claim 31 has been amended to recite:

An apparatus for treatment of subcutaneous tissue comprising: at least one ultrasonic generator configured to generate ultrasonic vibrations; at least one substantially plano-concave lens disposed immediately adjacent the at least one ultrasonic generator to focus the ultrasonic vibrations at a focal point within the tissue; a chamber configured to at least partially enclose the at least one ultrasonic generator and the at least one substantially plano-concave lens and being uniformly pressurized therein during treatment, wherein each of the at least one ultrasonic generator is substantially equally spaced from an adjacent one along a substantially semi-circular plane, and wherein a focal plane of the at least one ultrasonic generator is transverse to a portion of the chamber; and a mounting mechanism configured to mount the at least one substantially plano-concave lens and the at least one ultrasonic generator to be moveable together to move the focal point.

Similar limitations as the limitations underlined above for Claim 31 have been added to independent Claim 36.

Oppelt et al. is directed to a therapy apparatus for the treatment of tissue in the body. The apparatus includes two ultrasound transducers 1 and 2 that are applied to the body 3 of a patient. The ultrasound transducers 1 and 2 include a chamber housing the

various components of the ultrasound transducers 1 and 2. Several of the components include a disc-shaped piezoceramic element 9, a lens 10, a backing 11 and a carrier member 12. The chamber is non-compartmentalized and is configured for being entirely filled with a fluid during treatment of the patient as shown by dashed lines in Figures 1, 2, 4 and 5.

Hassler is directed to a shock wave source having several electro-acoustic transducers 1 arranged in a concave surface and housed within a housing or chamber 2, having an exit aperture 3 for the shock wave generated by the transducers 1. The exit aperture 3 is closed by a flexible membrane 4. The housing 2 is non-compartmentalized and according to Hassler the entire housing is filled with a fluid during treatment. Hassler states the “volume bounded by the housing 2 and the membrane 4 is filled with a fluid, for example water, as a propagation medium for the shock waves.” See column 5, lines 4-19, in conjunction with Figure 3.

Sekino et al. is directed to several embodiments of an ultrasonic treatment system. Each embodiment includes a holding member, such as water bag 7, which is filled with an ultrasonic transmitting medium and an ultrasonic wave generator 5. The holding member is disposed between the ultrasonic wave generator 5 and the human body 2 as shown by the Figures. The holding member of the ultrasonic treatment system 1, as shown by the Figures, is non-compartmentalized and is analogous to a housing or chamber.

Fry et al. is directed to a transducer assembly for visualization and treatment of transcutaneous and intraoperative sites. The transducer assembly provides a substantially enclosed chamber 103 for housing in combination a visualization transducer 28 and a

treatment transducer 24, each of which are movable with both linear and rotary degrees of freedom. The treatment transducer 24 is illustrated by Figure 3 and it includes spaces or compartments 165 and 185, where during treatment a positive differential pressure is maintained in space 185 relative to the pressure in space 165 via flow access channels 189 into column 190 and well 191. See column 6, lines 42-50 in conjunction with Figure 3. Hence, at least one region within the transducer assembly 24 has a different pressure than another region within the transducer assembly 24 during treatment. The chamber 103 is configured for being filled with water via tubing member 104, such that the water comes into contact with both transducers 24 and 28 during treatment of the patient.

Neither Oppelt et al., Hassler, Sekino et al. nor Fry et al., taken alone or in combination, disclose or suggest the limitations recited by Applicants' independent Claims 24, 31 and 36. In particular, neither Oppelt et al., Hassler, Sekino et al. nor Fry et al., taken alone or in combination, disclose or suggest an apparatus for treatment of subcutaneous tissue comprising at least "a chamber configured to at least partially enclose the means for generating ultrasonic vibrations and the substantially plano-concave lens and being uniformly pressurized therein during treatment, wherein the means for generating ultrasonic vibrations includes a plurality of generator means for generating ultrasonic vibrations, wherein each of the plurality of generator means is substantially equally spaced from an adjacent one along a substantially semi-circular plane, and wherein a focal plane of at least one generator means is transverse to a portion of the chamber," as recited by Applicants' Claim 24.

Further, neither Oppelt et al., Hassler, Sekino et al. nor Fry et al., taken alone or in combination, disclose or suggest an apparatus for treatment of subcutaneous tissue

comprising at least “a chamber configured to at least partially enclose the at least one ultrasonic generator and the at least one substantially plano-concave lens and being uniformly pressurized therein during treatment, wherein each of the at least one ultrasonic generator is substantially equally spaced from an adjacent one along a substantially semi-circular plane, and wherein a focal plane of the at least one ultrasonic generator is transverse to a portion of the chamber,” as recited by Applicants’ Claim 31. (Emphasis Added)

Finally, neither Oppelt et al., Hassler, Sekino et al. nor Fry et al., taken alone or in combination, disclose or suggest a method for treatment of subcutaneous tissue comprising at least the step of “providing an apparatus including ... a chamber configured to at least partially enclose the at least one ultrasonic generator and the at least one substantially plano-concave lens and being uniformly pressurized therein during treatment, wherein each of the at least one ultrasonic generator is substantially equally spaced from an adjacent one along a substantially semi-circular plane, and wherein a focal plane of the at least one ultrasonic generator is transverse to a portion of the chamber,” as recited by Applicants’ Claim 36. (Emphasis Added)

Dependent Claims 25-30, 32-35 and 37 depend from either independent Claim 24, 31 or 36, and therefore include the limitations of Claims 24, 31 or 36. Accordingly, for at least the same reasons given for Claims 24, 31 and 36, Claims 25-30, 32-35 and 37 are believed to contain patentable subject matter.

In view of the newly presented claims and remarks, withdrawal of the rejections under 35 U.S.C. §§102(b), 103(a) and allowance of all the claims are respectfully requested.



It is respectfully submitted that all claims presently pending in the application, namely, Claims 24 and 26-40, are believed to be in condition for allowance and patentably distinguishable over the art of record.

If the Examiner should have any questions concerning this communication or feels that an interview would be helpful, the Examiner is requested to call the undersigned attorney at 631-501-5701.

Respectfully submitted,

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